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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,324	10/07/2005	Hans Loibner	4518-0111PUS1	8937

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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
09/25/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,324	LOIBNER ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTIONDETAILED ACTION

1. Claims 1-28 are all the pending claims subject to lack of unity restriction.

Lack of Unity: Restriction

2. Restriction is required under 35 U.S.C. 121 and 372.

The claims of the present application relate to a recombinant anti-idiotypic murine IgG2a antibody having hamster or primate glycosylation. The problem to be solved is the provision of monoclonal antibodies for use in pharmaceutical preparations presenting improved immunogenic properties. The effect linked to the glycosylation is that of Mab 17-1A improving ADCC measured in vitro with human effector cells and human cancer cell lines without changing the response of a rhesus monkey to the antibody, and in another example, for the IgG2a Le-Y anti-idiotypic antibody, the presence of primate glycosylation improves (increases) the immunogenicity of the antibody in Rhesus monkey. Thus the improved immunogenic properties would mean that for passive immunization, the antibody should induce less response in order to act and not be rejected and still provide the expected effect, whereas in active immunization, the antibody should induce an improved humoral immune response observed as, for example, higher titer or higher affinity for the antigenic determinants. Because generic Claim 1 encompasses antibodies having the property of Mab 17-1A, which when produced in human CHO cells would have been human (primate) glycosylated, and showed no difference between the elicited response compared to the

hybridoma-produced Mab 17-1A, the invention is not considered to be a contribution over the prior art.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same technical features, can be recognized, the requirements of unity of invention are said to be met.

Hellstrom et al. (EP-A-0759442; published 2/26/97; cited in the IPER report enclosed with the filing of 10/7/05 and cited in the IDS of 8/22/07) discloses an anti-idiotypic murine IgG2a antibody (p. 43, last paragraph; p. 46, line 35- p. 48, line 8; Table XVI) which has improved ADCC measured in vitro with human effector cells and human cancer cell lines. The production of recombinant antibodies by genetic engineering would have been routine for one of skill in the art therefore the vectors, e.g., commercially available multicistronic vectors containing IRES elements, cell lines transformed with vectors to express the product were well known in the art in order to produce and select the recombinant antibody.

As no technical feature(s) can be distinguished which, in light of the prior art reference, could be regarded as special technical features on which a unifying concept could be based, there is no single inventive concept underlying the plurality of claimed inventions.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to a recombinant anti-idiotypic murine IgG2a antibody having hamster or primate glycosylation.

Group II, claim(s) 14 and 15, drawn to a vaccine comprising a recombinant anti-idiotypic murine IgG2a antibody having hamster or primate glycosylation in a pharmaceutical formulation.

Group III, claim(s) 16-28, drawn to a multicitronic construct for producing a recombinant anti-idiotypic murine IgG2a antibody having hamster or primate glycosylation, a vector comprising the multicistronic expression construct, cell transformed with the vector, and a method for producing the antibody from the cell transformed with the multicistronic construct.

4. Three different products are presented in Groups I-III. The products of Group I and II share a common property or activity but do not share common core structures. The anti-idiotypic antibody of Group I is not required to produce a preventative effect whereas the antibody of Group II is required to be immunogenic and produce an preventative effect as a vaccine formulation. Thus the inventions of Groups I and II are distinguishable based on their intended biological properties. The antibody of Group I and the vaccine antibody of Group II are distinct from the multicistronic construct for producing the antibody because both the antibodies comprise amino acid sequences and are not designed for expressing a protein, whereas the construct comprises

nucleotide sequences encoding the antibody in addition to elements for expressing the antibody under host cell conditions. One could not use the antibodies proteins and the construct interchangeably and expect the same result. Thus the inventions of Groups I-III are distinguishable based on their different structures and intended biological properties.

Election of Species

5. If Group I is elected, then species (antigen) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) peptide or proteins such as EpCAM, NCAM, CEA, and T cell peptides

Specie B) carbohydrates such as Lewis Y, Sialo-Tn, and GloboH

Specie C) glycolipids such as GD2, GD3, and GM2

The species are independent or distinct because each is well recognized in the art as being expressed on or by different cell types, having different structures, different cognate ligands and signal interactions. For example, any commercial protein database (e.g., SwissProt) lists this information. In addition, The Human Protein Reference Database (HPRD.org) describes the tissue expression patterns, structural and functional properties and any disease correlates for the species of antigen. The species are not obvious variants or overlapping and one of ordinary skill in the art would appreciate that based on these reference disclosures alone or in combination, that these species are distinct and separate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-8 and 10-13 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER